

Application No.: 10/584,105  
Attorney Docket No.: 66090-005US0  
First Applicant's Name: Mansour Samadpour  
Application Filing Date: August 21, 2007  
Final Office Action Dated: June 17, 2011  
Date of Response: December 19, 2011  
Examiner: Kevin Joyner

### **REMARKS**

Claims 1-30 are pending.

Claims 22-30 are withdrawn.

Claims 1-21 stand rejected by the Examiner.

Claims 1, 11-13 and 20-22 have been amended herein.

Applicant thanks the Examiner for withdrawing the prior indefiniteness rejections and the 35 U.S.C. § 103(a) obviousness rejections over Baker, Jr. et al. (U.S. Patent No.6,635,676) (hereinafter "Baker") in view of Beerse et al. (U.S. Patent No. 6,294,186) (hereinafter "Beerse") in view of Applicant's last Amendments and remarks.

### ***Rejection under 35 U.S.C. § 103***

The Examiner has rejected claims 1, 2, 4-13 and 15-21, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Sawhney et al. (U.S. Patent No.6,387,977) in view of Baker, Jr. et al. (U.S. Patent No.6,635,676; hereinafter "Baker") for reasons stated in the Office Action ("OA").

Specifically, the Examiner alleges, with respect to claims 1, 2, 4-13, and 15-21, that Sawhney discloses all the elements of Applicant's cited claims except for the amount of stabilizer or the surfactant, but that Baker makes these additional disclosures (see page 4 of the OA) and, thus, in combination, allegedly obviates the claims.

The Examiner states that Sawhney does not teach the amount of stabilizer, the surfactant, or that the composition is heated, but that Baker nonetheless does for reasons stated in the OA.

### **Applicant's traversal:**

Applicant respectfully traverses the rejection based on the presently recited claim amendments, and in view of the limited teachings of Sawhney and Baker. Sawhney has been *fundamentally* misapplied. Specifically, in stark contrast to Applicant's adherent sacrificial barrier compositions, the surface coatings of Sawhney are (i) not only photo-cross-linked

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throughout thus forming a polymerized adherent material, but additionally (ii) are “**tightly bonded**” (in fact “tenaciously” adhered) to the surface, and thus are NOT partially transferable, either from the polymerized adherent material or from the surface as urged by the Examiner.

*Sawhney*. Sawhney disclose a “priming” process in which the surface (e.g., tissue) is initially stained with a photoinitiator, then a polymer solution of polymer monomers (and having some of the same photoinitiator) is applied over the primed surface to form an “absorbed layer.” “On exposure to light, the resulting system polymerizes at the surface, giving excellent adherence.” The system is “highly adherent to the surface.” Certain embodiments involve joining to tissue surfaces, wherein first and second tissue surfaces are prestained with photoinitiator, and a layer of polymerizable monomer is placed therebetween, followed by polymerization by exposure to light, whereby “strong adhesion is obtained between the two surfaces (see, e.g., ABSTRACT and col. 4, ll. 5-27; see also col. 2, ll. 3-48, teaching “highly adherent,” “excellent adherence,” “maintaining high adherence at the interface,” “sealing junctions” between tissue surfaces,” etc.; see also col. 8, ll. 46-65 teaching tenacity of adherence; see col. 9, ll. 1-1-10, teaching bonds between substances, “tightly adhered,” “bond together,” etc.). Sawhney teaches that an object of the invention is “increasing the thickness of polymeric materials which can be ‘tethered’ to a tissue surface or other substrate” (col. 2, ll. 15-18). It is, therefore, *explicitly* clear that once the Sawhney monomer layer is polymerized, it is not a sacrificial layer, and rather remains intact and strongly adhered and “**tethered**” to the surface, in fact, so much intact and tethered that one can use this method to effectively glue two pieces of tissue together in the methods of Sawhney. It is explicitly clear, therefore, that the layers of Sawhney **cannot** be sacrificial in the sense claimed Applicant.

Applicant respectfully points out in this regard that the Examiners’ statement at page 3 of the OA that Sawhney teaches “wherein at least part of the adherent antimicrobial barrier composition will be intrinsically transferred (if only minimally) between the surface and the cutting instrument during cutting” is blatantly incorrect. Sawhney teaches just the opposite; namely that a tightly adhered/bound/tethered polymerized intact layer is used, in fact, to hold to

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surfaces together. Sawhney does not teach adherent *sacrificial* barrier materials as presently claimed.

**Baker.** The limitations of Baker have already been discussed and rebutted in the prosecution record. Additionally, the passage cited by the Examiner (col. 36, line 48 to col. 37, line 7) does not teach or suggest treating cutting implements in methods of cutting, and rather teaches treating devices that are to be deposited in contact with tissue for long periods of time (e.g., staples, zippers and catheters).

Moreover, the compositions of Baker are fundamentally different from the polymerized layers of Sawhney and combining Baker with Sawhney would render Sawhney inoperative for its explicitly stated purposes.

Applicant's claim already recites "wherein at least part of the adherent antimicrobial barrier composition is transferred between the surface and the cutting instrument during cutting," which effectively distinguishes the claimed subject matter from Sawhney, alone or in combination with Baker or any other asserted art. In view of the Examiner's comments, however, Applicant has nonetheless amended claim 1 to recite "wherein at least part of the adherent sacrificial antimicrobial barrier composition is transferred between the surface and the cutting instrument during cutting...." Conforming amendments have been made to claims 11-13 and 20-22. The amendments, fully supported by the originally-filed specification (see e.g., at page 14, under Example 4; see also original claim 11, etc.), serves to further clarify the unique sacrificial aspect of Applicant's claimed adherent antimicrobial barrier composition. There is no teaching whatsoever in Sawhney of sacrificial transfer of the tightly adhered, polymerized Sawhney layers, and in fact Sawhney teaches just the opposite, and thus fundamentally and profoundly teaches away from Applicant's claimed subject matter, and moreover combining Baker with Sawhney would render Sawhney inoperative for its explicitly stated purposes.

Applicant, therefore, respectfully requests withdrawal of the rejection based on Sawhney, alone or in combination with Baker.

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***Further rejection under 35 U.S.C. § 103***

The Examiner has rejected claims 3 and 14, under 35 U.S.C. § 103(a), as allegedly being unpatentable over Sawhney. et al. (U.S. Patent No.6,387,977) in view of Baker, Jr. et al. (U.S. Patent No.6,635,676; hereinafter “Baker”) as applied to claims 1 and 12 above, and further in view of Beerse et al. (U.S. Patent No. 6,294,186) (hereinafter “Beerse”) for reasons stated in the OA.

The Examiner states that neither Sawhney nor Baker disclose sodium alginate, but that Beeres nonetheless does.

Applicants respectfully traverse this rejection, because Beers, alone or in combination, fails to cure the deficiencies of the primary and/or secondary references.

Sawhney and Baker have been discussed and rebutted above.

***Beerse.*** While Beerse may arguable teach the use of alginate, there is no suggestion whatsoever in Beerse that an “adherent” barrier acts to physically block access by microorganisms. Rather, the main teaching of Beerse is that viruses may be inactivated by contact with a particular antimicrobial, benzoic acid, when this is applied to the skin. The proposed applications such as application to human, or application to hard surfaces (column 4, lines 1-5), obviously do not involve a thick “adherent” barrier, since, clearly, it would be undesirable to have a thick coating of substance on a floor or countertop, or on human skin, and in this respect would not reasonably motivate the combination of Beerse with either Baker or Sawhney. Rather, the mode of Beerse appears to be, and would be understood to be, *transient* application of benzoic acid in order to achieve a specific anti-virus action caused by a specific antimicrobial. Additionally, Beerse (at column 4, lines 15-25) is highly suggestive that a thick coating is **not intended**, since the claimed antimicrobial action persists only for a few hours, at most. Moreover, as described by Beerse (at column 17, lines 34-40), the purpose of a gel additive is not to provide adhesion, but rather to provide particular “rheological characteristics” to the composition. In these respects, therefore, Beerse actually *teaches away* from Applicant’s

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claimed subject matter. This conclusion is bolstered by the discussion in Beerse (at column 12, lines 40-45), which indicates that low viscosity emulsions are preferred over those which are high viscosity, presumably more adherent, emulsions. Accordingly, due to the different motives for the use of gels in Beerse, a person of skill in the relevant art looking for information about "adherent" coatings would not be motivated to follow or utilize the Beerse teachings and would actually be discouraged from doing so. Moreover, as stated above, combination of Baker with Sawhney would render Sawhney inoperative for its stated purpose as discussed above.

Finally, as acknowledged by the Examiner, neither Baker nor Beerse teaches, suggests, or motivates use of a cutting implement, or a method of reducing or preventing transfer of microbial contamination to or from a surface being cut as presently claimed. Applicant respectfully contends that the asserted rejection is improperly premised on hindsight, particularly in view of the fact that aspects of Baker and Beerse actually *teach away* from Applicant's claimed subject matter as discussed herein. Moreover, Iwai, not asserted here but previously asserted, teaches only aqueous washing solution which may even be applied in the form of "mist" continuously generated in a "chamber" (Iwai at page 3, paragraph 0040-0041, also 0044). Iwai, therefore, operates not by applying a "layer" but rather by continually applying a mist, or by repeatedly applying a non-adherent, non-persistent solution for short periods of time (Iwai at paragraph 0047). This is a fundamentally different mode of operation than applying an adherent layer containing a gel as presently claimed. Iwai teaches nothing more than simply washing of a carcass with a water solution, and moreover directly *teaches away* from the idea of a persistent coating, by indicating that contact between the solution and the meat should be limited to only short periods of seconds, in order to avoid excessive water absorption by the meat (Iwai at paragraph 0047). There would be no motivation to combine Iwai with Sawhney, Baker or Beerse.

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**APPLICABLE LAW:**

***Obviousness.*** In *KSR International Co. v. Teleflex, Inc.* 127 S.Ct. 1727, 2007 (herein referred to as “KSR”), the Supreme Court stated that the Graham factors ((1) scope and content of the prior art, (2) difference between claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations; Graham v. John Deere Co., 383 U.S. 1 (1966)) continue to define the inquiry that controls the obviousness analysis. Additionally, under KSR, the TSM test is valid provided that such application does not require an overly rigid or explicit application of the asserted prior art. Accordingly, as already stated in the record, and in keeping with KSR, to establish a *prima facie* case of obviousness there must be: (i) a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art (POSITA), to modify the reference or to combine reference teachings; (ii) a reasonable expectation of success; and (iii) the prior art reference(s) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and knowledge generally available to POSITA, and not based on Applicant's disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); and see MPEP §§ 2143-2143.03). Therefore, to support a conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Moreover, there can be no reasonable expectation of success where the art, alone or in combination, *teaches away* from the invention.

***Inventions and asserted references must be considered as a whole.*** Importantly, even where a *prima facie* case is established, such case is rebuttable, and the proper inquiry involves consideration of inventions as a whole (*In re O'Farrell*, 853 F.2d 894, 903 (1988)). In determining the differences between the prior art and the claims, the question under 35 U.S.C.

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103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). In *Diamond v. Diehr* (450 US 175, 209 USPQ 1) (U.S. 1981), the *Diehr* Court determined “[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the [35 U.S.C. § 101] analysis.” Claims have a synergistic effect, so that if a claim contains elements A, B, C, and D, it is not proper to attack each of A, B, C, and D in isolation as four separate elements. The USPTO and the courts must view the claim as a whole under 35 U.S.C. § 101.

Applicant respectfully points out, therefore, that under U.S. patent law, that when multiple references are asserted in combination, each reference must nonetheless be individually considered as a whole, and that the Examiner cannot, therefore, indiscriminately parse and combine elements from multiple references and ignore how those elements function in each reference “as a whole.”

In the instant case, while Iwai may arguably teach cutting, this teaching is of cutting in the sole and required context of a transient aqueous washing solution where contact between the solution and the meat is limited to only short periods. The Examiner's assertion of Iwai, therefore, is unsupportable because in combining the teachings of Iwai with those of Baker and Beerse, the Examiner has not considered Iwai “as a whole” as required under U.S. patent law.

Likewise, but combination of Baker and or Sawhney gelling agents would be contrary to the requirement in Iwai of a transient aqueous washing solution and, thus, such combination ignores the references as a whole and would further render Sawhney and/or Baker and/or Iwai inoperable for their respective applications (render the references unsatisfactory for there respective intended purposes (MPEP § 2143.01)). Similarly, the mode of Beerse comprises, *transient* application of benzoic acid in order to achieve a specific anti-virus action caused by a specific antimicrobial. There is no suggestion whatsoever in Beerse that an “adherent” barrier acts to physically block access by microorganisms, and the Beerse applications, such as

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application to human or hard surfaces (column 4, lines 1-5), obviously do not involve a thick "adherent" barrier.

Applicant respectfully contends that the asserted rejections are not supportable when, in considering the references in combination, each reference is nonetheless considered as a whole. Applicant further respectfully contends that the rejection is improperly premised on hindsight, particularly in view of the fact that aspects of Sawheny, Baker, Beerse and Iwai actually *teach away* from Applicant's claimed subject matter as discussed below.

Applicant, therefore, respectfully requests withdrawal of the Examiner's obviousness rejections.



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